HFI-35 ~ OKA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MS 23

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

March 5, 2001

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Ray C. Smith, President
Lancer Medical Services, Inc.,
777 North Loren Avenue
Azusa, CA 91702

WL-26-01

Dear Mr. Smith:

During an inspection of your firm located in Azusa, California, on January 30 to February 15, 2001, our investigators determined that your firm manufactures general purpose steam sterilizers. General purpose steam sterilizers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection disclosed that these devices are adulterated within the meaning of Section 510(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish, maintain and control a quality system that is appropriate for the specific devices manufactured. [21 CFR 820.20]. For example,

- Management with executive responsibility has not ensured that quality system requirements are effectively established and effectively maintained.

- Management with executive responsibility has not established a policy and objectives for, and commitment to, quality for specific devices manufactured.

- No quality plan defining the quality practices, resources, and activities relevant to devices that are designed and manufactured has been established or implemented.

- No quality system procedures and instructions have been established.

2. Failure to establish procedures and to conduct quality audits to assure that quality system is in compliance with established quality system requirements and to determine the effectiveness of the quality system [21 CFR 820.22].

3. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100].

Additionally, your general purpose steam sterilizers are adulterated within the meaning of Section 501(f)(1)(B) of the Act in that they are Class III devices under Section 513(f) of the Act and there is no approved application for premarket approval in effect pursuant to Section 515(a), or an approved application for investigational device exemption under Section 520(g).

Additionally, your general purpose steam sterilizers are misbranded within the meaning of Section 502(o) of the Act in that a notice or other information for the devices was not provided to the FDA as required by Section 510(k) and that devices were manufactured in an establishment not duly registered under Section 510 and were not included in a list required by Section 510(j).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please advise us of your decision with respect to the 4 "LMS Passport" and "President" sterilizers that were identified as being sold to medical facilities and remaining in the marketplace.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director
Los Angeles District Office

cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320